IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO WAVE 5 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS'MOTION TO EXCLUDE OR OTHERWISE LIMIT THE OPINIONS AND TESTIMONY OF DEFENSE EXPERT MARSHALL SHOEMAKER, M.D.

Plaintiffs respectfully request that this Court exclude or otherwise limit the opinions and testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson's expert Marshall Shoemaker, M.D. ("Dr. Shoemaker"). In support of their motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Shoemaker is board-certified in Obstetrics and Gynecology, and he currently owns his own practice in Fairhope, Alabama. Plaintiffs do not challenge his qualifications as such. Dr. Shoemaker serves as a paid preceptor for Gynecare Women's Health and Urology on TVT-S, LSH, Prolift, and Office Thermal Ablation; additionally, Dr. Shoemaker serves as a paid Coloplast Preceptor on Axis Dermis, TVT-Atlas, and Exair Mesh. *See generally* Exhibit B (Shoemaker Report: Prolift); *see generally* Exhibit C (Shoemaker Report: TVT); *see* Exhibit D (Deposition of Marshall Shoemaker, M.D., 7/21/17, 9:13-23, 14:6-19; *see* Exhibit H (Shoemaker curriculum vitae). Dr. Shoemaker has been hired by Ethicon to prepare a general report on the

design, safety, and efficacy of the Gynecare TVT, TVT-O, TVT-Abbrevo, and TVT Exact midurethral slings and Gynemesh PS Transvaginal Mesh, Prolift+M, and Proisma devices.

Dr. Shoemaker's opinions in both of his general reports proffer that each device listed above is "safe and effective and provide[s] adequate warnings and instructions to doctors." *See* Exhibit B and C. Further, Dr. Shoemaker offers his opinions concerning the adequacy of the IFUs ("Instructions for Use"), complications associated with these products compared to other surgical options to treat Pelvic Organ Prolapse and SUI conditions, as well as all other opinions related to the design and performance of these products, positions statements concerning the safety of these devices made by Ethicon, professional societies, or the FDA, and finally the design and material properties of Ethicon's TVT, TVT-O, TVT Abbrevo, and TVT Exact midurethral slings, as well as the Gynemesh PS Transvaginal Mesh, Prolift+M, and Prosima devices.

Dr. Shoemaker concludes his reports by offering opinions on the material properties of polypropylene mesh including degradation, cytotoxicity, contraction of mesh, adequacy of pore size and weight of the mesh, lack of clinical difference between laser and mechanically cut mesh, and the adequacy of any and all information given by Ethicon to physicians regarding TVT, TVT-O, and Pelvic Organ Prolapse devices.

As explained below, Dr. Shoemaker is unqualified to offer opinions on the adequacy of Ethicon's IFUs and informational material, as well as the design and scientific properties of mesh devices and midurethral slings. Dr. Shoemaker's experience in the field of Obstetrics and Gynecology does not render all of his opinions admissible.

LEGAL STANDARD

"A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." F.R.E. 702. In the context of Rule 702, "'knowledge connotes more than subjective belief or unsupported speculation." *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579, 590 (1993). Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the matters upon which she will opine are clearly within her area of expertise." *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D. N.C. 2007).

If the expert is qualified, "[t]he U.S. Supreme Court [has] established a two-part test to govern the admissibility of [the] expert testimony under Rule 702—the evidence is admitted if it 'rests on a reliable foundation and is relevant.'" *Tyree v. Boston Scientific Corp*., 54 F.Supp.3d 501, 516 (S.D. W. Va. 2014) (*quoting Daubert*, 509 U.S. at 597). Although "[t]he proponent of expert testimony does not have the burden to 'prove' anything to the court," he or she must nonetheless "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id*. (*quoting Md. Cas. Co. v. Therm-O-Disc, Inc*., 137 F.3d 780, 783 (4th Cir. 1998)).

The Supreme Court has provided a non-exhaustive list of factors for a judge to consider in applying F.R.E. 702: "(1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known

or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Cooper v. Smith & Nephew, Inc*., 259 F.3d 194, 199 (4th Cir. 2001) (*citing Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999); *Daubert*, 509 U.S. at 592-94). "The inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir.1999) (*quoting Daubert*, 509 U.S. at 594-95). Even so, "'[e]xpert witnesses have the potential to be both powerful and quite misleading[;]' the [trial] court must 'ensure that any and all scientific testimony . . . is not only relevant, but reliable.'" *Tyree*, 54 F.Supp.3d at 516 (quoting *Cooper*, 259 F.3d at 199).

ARGUMENT

I. Dr. Shoemaker's General Opinions Regarding the Adequacy of the IFUs and "Surgeon's Resource Monograph" for the TVT, TVT-O, TVT-Abbrevo, and TVT-Exact Midurethral Slings, as well as Gynemesh PS Transvaginal Mesh, Prolift+M, and Prosima Devices Should Be Precluded or Limited.

Dr. Shoemaker is not qualified to offer general opinions or proffer testimony on the adequacy of IFU ("information for use") pamphlets or other Ethicon-made informational material because personal, clinical experience is not an adequate foundation for such testimony. Dr. Shoemaker has no training or familiarity with the FDA 510(k) approval process, which requires "device manufacturers … to notify the FDA of their intent to market a medical device …,"[1] and he has no experience in designing IFUs or selecting medical articles or peer-reviewed medical literature to include in IFUs. In his deposition, Dr. Shoemaker stated numerous times that he relies on his own clinical experience with medical

[1] U.S. Dep't of Health and Human Services, *U.S. Food & Drug Administration: 510(k) Clearances*, https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm (last updated January 25, 2017).

devices to determine their safety and efficacy and to determine which medical literature to rely on to guide his opinions on safety and efficacy. *See* Exhibit D at 232:4-17; 242:11-18. As this Court has previously held, medical experts are not qualified to offer opinions regarding the adequacy of a corporate defendant's IFU that accompanies a mesh device when marketed, based only on their own experience. *See Sederholm v. Boston Scientific Corp*., C. A. No. 2:13-cv-12510, 2016 WL 3282587, at *13 (S.D.W.Va. June 14, 2016) (excluding urologist's expert opinions on the adequacy of defendant's IFU that he based solely on the risks he observed in his practice.).

Moreover, in his first deposition, Dr. Shoemaker states that when he was forming his opinions about the safety and efficacy of Prolift, he reviewed and relied on the peer-reviewed medical literature that Ethicon provided to him and other doctors regarding Prolift. *See* Exhibit D at 248:9-22. This is problematic.

For example, "mesh shrinkage" was heavily discussed during Dr. Shoemaker's depositions. Conflicting evidence and scientific viewpoints on this issue highlight the discrepancies between the medical literature and personal clinical experience regarding the use of polypropylene mesh, thus proving that opinions based on personal clinical experience should be precluded or limited at trial.

First, Ethicon has a duty to provide its preceptors and doctors with up-to-date information, statistics, and peer-reviewed medical literature on their medical devices in order for these preceptors and doctors to adequately inform their colleagues and patients about all of the risks, complications, and benefits of using these devices. Ethicon failed to include multiple peer-reviewed medical articles in the IFUs that discussed all possible complications with mesh devices. One article in particular discussed a complication of "shrinkage" with

hernia mesh.[2] Although hernia mesh and vaginal mesh are not identical, this article noted that "[a]ll available meshes, regardless of their composition, experience a 20% to 50% reduction in their initial size. Factors of the mesh itself and the surrounding tissue inflammatory response contribute to this phenomenon."[3] Although Dr. Shoemaker states he was not aware of this article, Ethicon had a duty to include this information not only in the Gynemesh PS Transvaginal Mesh IFU, but any and all mesh IFUs to ensure that the preceptors and doctors were aware that *any* mesh product could present with a "shrinkage" complication. However, Ethicon did not fulfill this duty:

> 1 are you familiar with the name
> 2 Axel Arnaud, A-R-N-A-U-D?
>
> 3 A. No. Is he a urologist in Houston?
>
> 4 Q. He's from Ethicon. He's with Ethicon. Do
> 5 you recall at all seeing an email dated July of 2004
> 6 where he suggested adding, quote, unquote, "mesh
> 7 shrinkage as an additional adverse reaction in the
> 8 Prolift IFU"?
>
> 9 A. I do not remember that.
>
> 10 Q. Do you recall any type of follow-up email
> 11 from a Sean O'Bryan from Ethicon regulatory affairs
> 12 who states:
> 13 "If mesh shrinkage is a
> 14 real issue, we have an
> 15 obligation to put it in"?
>
> 16 A. I'm not familiar with that.

[2] *See generally* Miguel Angel Garcia-Urena, M.D., Ph.D. et al, *Differences in Polypropylene Shrinkage Depending on Mesh Position in an Experimental Study*, 193, Am J of Surg, 538, 538-542 (2007) (concluding that polypropylene meshes show a significant degree of shrinkage while scar tissue forms and the body heals); *See also* Benjamin Feiner, M.D. & Christopher Maher, *Vaginal Mesh Contraction; Definition, Clinical Presentation, and Management*, 115, Obstetrics & Gynecol, 325, 325-330 (2010) (stating "the pathological process that causes mesh shrinkage is progressive and there is a linear evolution of the contraction rate with time, raising the worrying possibility that mesh contraction syndrome that we have defined may be encountered more frequently in the future.").

[3] William S. Cobb et al, *The Argument for Lightweight Polypropylene Mesh in Hernia Repair*, 12, J Surg Innovation, 63, 67 (2005).

Q. Would you agree that if a company selling a mesh device recognizes that they have an adverse event, which is mesh shrinkage, whatever is causing the mesh –

A. Correct.

BY MR. RESTAINO:
Q. No one from Ethicon discussed with you that –

A. You know, I went to the launch meetings for Prolift and I went to lots of meetings with Prolift and we talked about lots of things. But I never remember thinking that was a problem, and they never brought it up as a problem that I know of, that I remember.

Q. And if you weren't seeing it in your own hands, in your own women, then would you agree you would have no basis for thinking it was a problem?

A. Yeah. I never thought it was a problem from my experience.

Q. And so no one at Ethicon told you we're having an issue, we're getting multiple reports of mesh shrinkage, we're thinking about adding it to the IFU; what do you think?

MR. WALKER: Object to the form.

A. They did not ask me that. And no one came to me and said: Are you having problems with this? I could not say I had.

BY MR. RESTAINO:
Q. And have you been shown anything from anyone at Ethicon regulatory affairs saying that if the new adverse reaction is added to the Prolift IFU, we will have to add it to the Gynemesh PS IFU also?

MR. WALKER: Object to the form.

A. No.

See Exhibit D at 121:1-21, 122:12-24, 23:1-16.

Additionally, due to Ethicon's negligence and Dr. Shoemaker's misplaced reliance, Dr. Shoemaker wrote in his expert report on TVT, TVT-O, TVT-Abbrevo, and TVT-Exact that "[m]esh shrinkage or contraction is discussed in the literature, but is somewhat of a misnomer. Scar tissue does shrink or contract during the healing process, and the scar tissue that is incorporated into the sling devices is no exception, but the mesh itself does not contract or shrink." *See* Exhibit C at 27. However, Dr. Shoemaker did not give reference to any article supporting this assertion, and Ethicon said nothing to this stipulation.

Second, as stated above, Dr. Shoemaker states in both of his expert reports and depositions that he generally concludes the safety and efficacy of medical devices based on his own clinical experience; however, his own clinical experience does not encompass every possible scenario that could occur with mesh products. For example, Dr. Shoemaker states that has never "completely excise[d] a full mesh" from a woman; he has only ever performed a partial excision due to "a small exposure." *See* Exhibit D at 29:14-21. This is indicative of the fact that Dr. Shoemaker may not personally know if "mesh shrinkage" actually occurs. Additionally, due to Ethicon's failure to disclose materials related to serious complications with the use of mesh devices to its preceptors and doctors, Dr. Shoemaker's reliance on Ethicon's IFUs and peer-reviewed medical literature is misplaced. In a study titled "*Mesh-related and Intraopertaive Complications of Pelvic Organ Prolapse Repair*," the authors wrote, "[t]he most frequent complications [with polypropylene mesh use] include vaginal mucosa erosion, mesh shrinkage, infections, pain, urinary tract disorders and a recurrence of prolapse."[4] Further, the study states that "[s]hrinkage of synthetic mesh after implantation is

[4] George Kasyan et al, *Mesh-Related and Intraoperative Complications of Pelvic Organ Prolapse Repair*, 67, Central European J of Urology, 296, 296-301 (2014).

one of the most serious complications."[5] However, this study was not cited by Ethicon, nor was it in Dr. Shoemaker's expert report. Thus, Dr. Shoemaker's reliance on his own clinical experience is unfounded with regards to mesh complications and his reliance on Ethicon's IFUs and "Surgeon's Resource Monograph" is misplaced. Therefore, his opinions on safety and efficacy are unreliable and should be excluded.

While "mesh shrinkage" is not the issue at hand with regards to Dr. Shoemaker's qualifications to speak to the adequacy of Ethicon's IFUs, this discussion highlights that Dr. Shoemaker has not taken into account all of the relevant medical literature on mesh devices, but rather relied on Ethicon to formulate his opinions on the safety and efficacy of these products. Additionally, as evidenced in his Expert Report, Dr. Shoemaker chose to rely on studies that he essentially "cherry-picked" to support his opinions. In one instance, Dr. Shoemaker relied on a study that not only showed plausible bias against native tissue repair, but also one that was relatively small in relation to other studies relevant to Dr. Shoemaker's conclusion that there are more native tissue repair failures than mesh failures. *See* Exhibit D at 91:13-24, 92:1-8. As this Court has observed, "[a]n expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.'" *Tyree*, 54 F. Supp. 3d at 520 (S.D.W. Va. 2014) (quoting *In re Rezulin Products Liab. Litig.*, 369 F.Supp.2d 398, 425 (S.D.N.Y. 2005) (quotations omitted)). Where, as here, the "relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*

Furthermore, in his expert report on the Gynemesh PS Transvaginal Mesh, Prolift+M, and Prosima, Dr. Shoemaker states that "[i]t is not necessary for the IFU" to "specify the

[5] *Id.*

frequency with which various complications occur" because "those rates are published in the medical literature that surgeons regularly review …." *See* Exhibit B at 34. However, Dr. Shoemaker stated in his deposition that he bases his conclusions on product safety and efficacy in terms of his experience, not his review of medical literature:

> Q. And that's in terms of your experience.
> What about your review of the medical literature?
> What has that informed your opinions in terms of the
> safety and efficacy of those products?
>
> A. I feel comfortable with the reviews that I
> have done both while I was placing the mesh and since
> the follow-up, the 17-year follow-up with TVT, we've
> had good safe effective mesh. I have no qualms with
> using the product.

See Exhibit D at 232:4-17.

Further, Dr. Shoemaker's expert reports discussed multiple studies that support his claim of safety and efficacy; however, his discussion of what many of the studies found differ from what the actual studies report. For example, Dr. Shoemaker relies on a Cochrane Review study to support his claim that "the use of a permanent polypropylene mesh demonstrates a lower rate of … prolapse on examination in contrast to native tissue repair …."[6] Yet, the study actually states,

> "[w]hile transvaginal permanent mesh is associated with lower rates of awareness of prolapse, repeat surgery for prolapse, and prolapse on examination than native tissue repair, it is also associated with higher rates of repeat surgery for prolapse or stress urinary incontinence or mesh exposure (as a composite outcome), and with higher rates of bladder injury at surgery and de novo stress urinary incontinence. The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery. While it is possible that in women with higher risk of recurrence the benefits

[6] Christopher Maher et al, *Transvaginal Mesh or Grafts Compared with Native Tissue Repair for Vaginal Prolapse*, Cochrane Database of Systematic Reviews, Art. No.: CD012079, 2016.

> may outweigh the risks, there is currently no evidence to support this position."[7]

See Exhibit B at 7.

Dr. Shoemaker did not include this finding in his report.

Finally, Dr. Shoemaker has not laid an adequate foundation to claim expertise regarding the adequacy of mesh IFUs and Ethicon's Surgeon's Resource Monograph. A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." *Oglesby v. General Motors Corp*., 190 F.3d 244, 250 (4th Cir. 1999). Relevant and compelling medical literature was absent from not only Dr. Shoemaker's expert report, general reliance list, and supplemental reliance list, but also Ethicon's IFUs and peer-reviewed medical literature given to Ethicon's preceptors and doctors. Therefore, due to the fact that Dr. Shoemaker's opinions regarding what he would consider to be an adequate IFU are based primarily on his personal clinical experience, his opinions concerning the adequacy of the TVT, TVT-O, TVT-Abbrevo, and TVT-Exact Midurethral Slings, as well as the Gynemesh Prolift Pelvic Floor Repair System, Gynemesh PS Transvaginal Mesh, Prolift+M, and Prosima IFUs are unreliable and should be excluded.

II. Dr. Shoemaker's General Opinions on the Design and Scientific Properties of the TVT, TVT-O, TVT-Abbrevo, and TVT-Exact Midurethral Slings, as well as the Gynemesh PS Transvaginal Mesh, Prolift+M, and Prosima Devices Should Be Precluded or Limited.

[7] *Id.*

Dr. Shoemaker is not qualified to offer general opinions or proffer testimony on the design and scientific properties of each device listed above. Specifically, Dr. Shoemaker lacks any specialized education, training, or experience that would qualify him to speak to the design of polypropylene mesh devices or the design of research studies on such devices. *See generally* Exhibits B and D. In fact, Dr. Shoemaker readily concedes that he is not an expert in designing mesh devices and has limited knowledge of the design process:

> 24 Q. And has Ethicon ever approached you and
> 1 asked you to work on or redesign any of their meshes?
>
> 2 A. They have not.

See Exhibit D at 27:24, 28:1-2.

Further, Dr. Shoemaker concedes that he has never been involved in designing a study looking at Prolift+M mesh versus native tissue repair:

> 5 Q. Okay. So no one has ever asked you to
> 6 design a prospective case -- or a retrospective case
> 7 control study looking at Prolift+M versus native
> 8 tissue repair?
>
> 9 A. I have not been involved.

See Exhibit D at 25:5-9.

Therefore, Dr. Shoemaker's opinions throughout his expert reports on such matters are unsound. Further, although Dr. Shoemaker contends that "clinically, he is an expert" in the field of gynecological pathology, as well as "somewhat an expert" in the field of epidemiological design of studies, he bases these assertions on his clinical experience. *See* Exhibit D at 24:1-24, 25:1-4. As stated above, clinical experience does not equate to expertise. During his residency, Dr. Shoemaker did not publish any papers or articles in any peer-reviewed medical literature and he has not published any article or report since. *See generally* Exhibit D. Additionally, Dr.

Shoemaker has never been invited to lecture at any national meeting on pelvic reconstructive surgery or mesh, and he has not held himself out as an expert in transvaginal mesh at any national meeting or conference. *See* Exhibit D at 20:8-18. Finally, Dr. Shoemaker has never received any training in material sciences and he does not consider himself an expert in the design and development of polypropylene stitch material devices, such as transvaginal mesh and midurethral slings. *See* Exhibit D at 15:20-24, 16:1-8. (emphasis added)

Despite the fact that Dr. Shoemaker admits that he is not an expert on designing mesh devices, he attempts to opine on the design and material properties of the TVT, TVT-O, TVT-Abbrevo, and TVT-Exact Midurethral Slings, as well as the Gynemesh PS Transvaginal Mesh, Prolift+M, and Prosima Devices, including the topics of degradation, cytotoxicity, the appropriate pore size and weight of mesh, and lack of clinical difference between laser and mechanically cut mesh. *See* Exhibits B and C at (1) 38-39, (2) 24-25. Specifically, Dr. Shoemaker proffers that the devices are "safe and effective and not defectively designed." Exhibits B and C at 39, 27. These opinions undoubtedly exceed the bounds of his qualifications.

Dr. Shoemaker did not use a reliable methodology in forming his opinions in his general report on the design of these products. Under *Daubert*, a literature review must be performed appropriately in order to be part of a reliable methodology; as part of this, the Court must find more than an expert's own "hypothesis and speculation." 509 U.S. at 590; *see also Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 473-74 (M.D.N.C. 2006) (excluding expert testimony based on a literature review, stating that it must be based on more than "hypothesis and speculation," that the review was "disconnected" and not derived by the scientific method.) Dr. Shoemaker failed to give a convincing story relaying that he relied on more than his own "hypothesis and speculation;" Dr. Shoemaker relied on studies and reports that did not meet

threshold standards of reliability. As espoused by *Benbouzid* and *Barber et al*, "previous expert opinions underlin[e] that 2 years should be considered as the minimal postoperative follow up for evaluating the outcome of pelvic floor reconstructive surgery."[8] *See* Exhibit E at 279:2-7. *Barber et al* also states that one cannot draw concrete conclusions from data collected before the 24-month threshold. *See* Exhibit E at 291:12-13. Not only did Dr. Shoemaker rely on studies in his expert report that fell below the 24-month threshold,[9] but he also relied heavily on "abstracts" of medical literature, as opposed to full peer-reviewed and published articles, and studies that had no comparator group, no control group, and no randomization. *See* Exhibit E at 276:9-24. Mere abstracts do not go through the same peer-review process as published articles, they are not published, and they do not contain all relevant data from the study, such as weaknesses and limitations. *See* Exhibit E at 281:5-13.

Moreover, in his depositions and expert reports on Gynemesh PS Transvaginal Mesh, Prolift+M, and Prosima devices, Dr. Shoemaker states that these devices were heavily studied, but he failed to give any citation to any referenced article supporting this contention:

21 Q. On 31 b, 10 lines down.
22 A. Okay.
23 Q. It's -- you write: "There were several
24 studies of Prosima which demonstrated its
1 efficacy and safety."
2 Do you see that?

3 A. Yes.

[8] Sabrina Benbouzid et al, *Pelvic organ prolapse transvaginal repair by the Prolift system: Evaluation of efficacy and complications after a 4.5 years follow up*, 19, Int'l J Urology,1010-1016 (2012); Matthew Barber et al, *Defining Success after Surgery for Pelvic Organ Prolapse*, 114, Obstetrics and Gynecol, 600, 600-609 (2009).
[9] Salil Khandwala, *Transvaginal Mesh Surgery for Pelvic Organ Prolapse: One-Year Outcome Analysis*, 19, Female Pelvic Med Reconstruc Surg, 84-89 (2013); Julie Quemener et al., *Rate of re-interventions after transvaginal pelvic organ prolapse repair using partially absorbable mesh: 20 months median follow-up outcomes*, 175, European J Obstetrics & Gynecol and Reproduc Biology, 194-98 (2014); Halina M. Zyczynski et al., *One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device*, 203, Am J Obstetrics & Gynecol, 587.e1-8 (2010).

4 Q. But there's no references there;
5 correct?

6 A. Correct.

7 Q. Can you tell me what studies you were
8 relying upon there?

9 A. There were just lots of ones I read,
10 and so I didn't document -- I mean, I didn't
11 document that.

12 Q. Okay.

See Exhibit E at 293:21-24, 94:1-12.

Additionally, Dr. Shoemaker spoke to the process that Prosima went through before it was introduced into the market, but evidently Ethicon relied solely on "internal studies" to conclude the safety and efficacy of such device:

8 MR. RESTAINO:
9 Q. So I was a little confused, then. When
10 you write, "Studies began in 2004, and the device
11 was not introduced until more than five years
12 later," what studies are you referring to?
13 Because they're not referenced.

14 A. I think they were doing internal
15 studies and they didn't like the results, so they
16 wanted to get more data before they put it out,
17 which was good for the company
.
18 Q. Now, I think -- as we were discussing
19 off the record yesterday, there is such a thing
20 as realtime *(sic)* where I could read through and I
21 could see your answer, but I think you said, I
22 think it went through internal studies. Do you
23 know that for sure?

24 A. I'm almost positive. I don't know all
1 the details about that. I've looked at that
2 before. I want to say it did. I want to say
3 they were doing internal studies and they didn't

> 4 like the data and they kept -- kept going on it
> 5 till they got -- till they felt like it was --
> 6 the data was complete.
>
> 7 Q. Without beating a dead horse, it says:
> 8 "Like Profit *(sic,* Prolift) it underwent many years of study
> 9 with development ..."
> 10 Did someone from Ethicon tell you that
> 11 or where are you getting that from?
>
> 12 A. I must have been told that.

See Exhibit E at 288:8-24, 89:1-12.

Both testimonies highlight the fact that it is unclear, at least with Prosima, what studies were actually conducted and what studies were referenced showing the safety and efficacy of the design of this device. Notwithstanding his clinical experience with these devices, Dr. Shoemaker is not qualified to offer opinions on the adequacy, safety, or efficacy of the structural or functional design of these devices.

Moving forward, Dr. Shoemaker additionally lacks qualification to offer opinions on the material properties of these devices, particularly with regards to degradation, cytotoxicity, the appropriate pore size and weight of mesh, and differences between laser and mechanically cut mesh.

First, with regards to cytotoxicity, Dr. Shoemaker has never removed a full mesh, he has never assessed the bacterial content of a partially removed mesh, and he believes that the probability of infection with mesh is "minimal." *See* Exhibit E at 301:2-18. However, one study, cited in Dr. Shoemaker's general reliance list, found that inflammation and infection could present months or years after an initial surgery:[10]

> 17 Q. "Conclusion: Inflammation around
> 18 alloplastic materials used to repair defects in

[10] U. Klinge, *Foreign Body Reaction to Meshes Used for the Repair of Abdominal Wall Hernias*, 165, European J of Surg, 665-73 (1999).

19 the abdominal wall persists for many years.
20 There was evidence of long-term wound
21 complications as a result of persistent foreign
22 body reaction. Further studies are required to
23 evaluate the long-term tissue response to these
24 materials."

1 Did I read that correctly?

2 A. Yes.

See Exhibit E at 306:17-24, 07:1-2.

Moreover, with regards to the TVT sling, Dr. Shoemaker posits that although one cytotoxicity assessment of this sling found "cytotoxic potential," the assessment "was not confirmed by the ISO Agarose diffuse method."[11] *See* Exhibit C at 26. However, this method is only "a good first step toward ensuring the biocompatibility of a medical device;"[12] this method may not always be dispositive of biocompatibility and it may not be the only method available. Consequently, due to Dr. Shoemaker's lack of scientific evidence stating otherwise, Dr. Shoemaker cannot give reliable and grounded opinions on the cytotoxicity of mesh devices and midurethral slings based solely on his own clinical experience.

Second, Dr. Shoemaker lacks qualification to speak to the degradation of polypropylene material in TVT, TVT-O, TVT-Abbrevo, and TVT-Exact Midurethral Slings, as well as the Gynemesh PS Transvaginal Mesh, Prolift+M, and Prosima devices. First, with regards to TVT slings, Dr. Shoemaker states in his report that "[b]ased on my positive experience using the slings in my patients and on my reading of the published literature, it is my opinion that clinically significant mesh degradation does not occur with Ethicon's products." Notwithstanding reference to a medical abstract, which, as stated above, lacks pertinent and

[11] *See A Practical Guide to ISO 10993-5: Cytotoxicity*, Med Device and Diagnostic Indus Magazine (1998) (stating, "[t]his standard presents a number of test methods designed to evaluate the acute adverse biological effects of extractables from medical device materials.")
[12] *Id.*

relevant information on the study, Dr. Shoemaker bases this conclusion on the fact that he has never seen a clinical significance with his naked eye. *See* Exhibit E at 328:1-7. As stated throughout, clinical experience does not equate to expertise, and Dr. Shoemaker is not an expert in degradation of polypropylene mesh devices and midurethral slings.

Third, Dr. Shoemaker lacks qualification to speak to the appropriate pore size and weight of mesh. He states in his expert report, "Gynemesh PS is a polypropylene mesh that has a pore size of greater than 75 microns, which is considered macroporous and desirable to allow passage of leukocytes and macrophages. The larger pore size allows capillary growth and integration of tissues into the pores that help support the prolapsed organ." *See* Exhibit B at 11. While this sounds scientific and legitimate, as stated above, Dr. Shoemaker was not involved in the design process or any other development process that would render him qualified to make such statements. This is further demonstrated by the fact that Dr. Shoemaker was unaware of that there are 400 yards of polypropylene stitch material present in these mesh devices. *See* Exhibit E at 310:1-17. With minimal to no knowledge of the actual material makeup of mesh devices, and relying on his own personal, clinical experience to posit multiple assertions about mesh products, Dr. Shoemaker cannot claim expertise on the material properties of mesh devices. *See* Exhibit E at 327:6-14.

Finally, Dr. Shoemaker lacks qualification to speak to the clinical differences between laser and mechanically cut mesh. It is evident in his deposition that Dr. Shoemaker did not fully understand why Ethicon started to use laser cut mesh, as opposed to mechanically cut mesh, even though he concedes to seeing a few emails from within Ethicon stating that laser cut mesh aids in "minimiz[ing] particle degradation." *See* Exhibit E at 332:17-24. Further, in his expert report on transvaginal mesh devices, Dr. Shoemaker states that "there have been concerns regarding

polypropylene degradation by high magnification images that show meshes with 'cracked' surfaces." *See* Exhibit B at 38. However, Dr. Shoemaker attempts to alleviate the potential effect of this finding by pointing to "methodological flaws" in the cited study and the, alleged, lack of peer-reviewed literature supporting degradation.[13] *See* Exhibit E at 335:10-22. *See* Exhibit – at 39. Notably however, Dr. Shoemaker did not find this study from his own research; he states he was given this study and that he "read something someone else had said" regarding this study and its lack of supportive peer-reviewed literature. *See* Exhibit E at 335:18-23. This study, authored by Clave et al, found that out of 100 cases of explant surgeries, 46% of arose out of exposure complications, thus leaving 54% due to infection and/or shrinkage.[14] Even if this study did not report these findings, Dr. Shoemaker did not give reference to any cited medical literature supporting his assertion that polypropylene material does not degrade, and his contention that he has not seen degradation in his personal clinical experience does not by any means render degradation impossible.

In conclusion, Dr. Shoemaker has not "come forward with evidence from which the court can determine" that he is qualified to testify regarding any of the above discussed topics. *Tyree, supra*. Dr. Shoemaker is not qualified to offer opinions on the adequacy of Ethicon's IFUs and informational material, nor is he qualified to offer opinions on the design and scientific properties of TVT, TVT-O, TVT-Abbrevo, and TVT-Exact Midurethral Slings or Gynemesh PS Transvaginal Mesh, Prolift+M, and Prosima Devices. Therefore, his testimony should be excluded.

CONCLUSION

For these reasons, Plaintiffs ask that this Court grant their motion and exclude or

[13] Arnaud Clavé et al, *Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants*, 21, Int'l Urogynecol J, 261, 263 (2010).
[14] *Id.*

otherwise limit the opinions and testimony of Dr. Shoemaker. Plaintiffs further request all other relief to which they are entitled.

Respectfully submitted,

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